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		OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER
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	DESIGNATED/ELECTI	ED OFFICE (DO/EO/US)	U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR
	CONCERNING A FILIN	IG UNDER 35 U.S.C. 371	09/581180
INTERÑA •	TIONAL APPLICATION NO. PCT/JP98/05236	INTERNATIONAL FILING DATE 20 November 1998	PRIORITY DATE CLAIMED 22 December 1997
-	INVENTION		
GRANU	LAR SWEETENER		
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	NT(S) FOR DO/EO/US ni ISHIDA, et al.		
Applicant	herewith submits to the United Star	tes Designated/Elected Office (DO/EO/US) th	e following items and other information.
1.		tems concerning a filing under 35 U.S.C. 371.	
2.		UENT submission of items concerning a filing	
3. ☒			
J	examination until the expiration of	in national examination procedures (35 U.S.C. of the applicable time limit set in 35 U.S.C. 37	71(b) and PCT Articles 22 and 39(1).
4.	A proper Demand for Internation	al Preliminary Examination was made by the	19th month from the earliest claimed priority date.
5.		ication as filed (35 U.S.C. 371 (c) (2))	
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7.		Application into English (35 U.S.C. 371(c)(2))).
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9. 🗔 🗆		to the claims under PCT Article 19 (35 U.S.C.	2717-727
10.	An oath or declaration of the inver		3/1(c)(3)).
11.2 0		ninary Examination Report (PCT/IPEA/409).	
12. 🗆	A translation of the annexes to the	e International Preliminary Examination Report	rt under DCT Article 26
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Items 1	13 to 18 below concern document(s) or information included:	
13. □	An Information Disclosure Statem	nent under 37 CFR 1.97 and 1.98.	
4.	An assignment document for recor	rding. A separate cover sheet in compliance v	with 37 CFR 3.28 and 3.31 is included.
5.	A FIRST preliminary amendment.		
	A SECOND or SUBSEQUENT p	reliminary amendment.	
6. 🗆	A substitute specification.		
7.	A change of power of attorney and		
8.	Certificate of Mailing by Express N	Mail	
9.	Other items or information:		
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	Notice of Priority PCT/IB/304		
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DESCRIPTION

GRANULAR SWEETENER

(Technical Field)

The present invention relates to a highly soluble sweetener granule (i.e., granular sweetener or granulated sweetener) containing Aspartame (hereinafter abbreviated as "APM") and Acesulfame K (hereinafter abbreviated as "ACE-K") as active ingredients.

(Background Art)

It is reported that the level of sweetness of APM which is an amino acid-based synthetic sweetener, is about 200 times that of sucrose in terms of weight ratio (Japanese Patent Application Publication (Kokoku) No. 31031/'72). When compared with sucrose which is regarded as a standard for evaluating sweetness characteristics, the profile of sweetness characteristics of APM is of such that it is weak in early taste (which means that the sweetener when placed in the mouth does not taste sweet so early as sucrose does), whereas it is strong in late taste (which means that the sweetener when placed in the mouth tastes sweet later than sucrose does). Accordingly, various approaches for the improvement of the sweetness profile of APM have been proposed mainly in terms of the late taste (for

example, Japanese Patent Application Laid-open (Kokai) Nos. 148255/'81, 141760/'83, 220668/'83 and the like), and a method for obtaining a more natural sweetness profile which is closer to that of sucrose, for example, by using APM in combination with sucrose has been also proposed (Japanese Patent Application Laid-open (Kokai) No. 152862/'82).

On the other hand, ACE-K is also a synthetic sweetener having a sweetness level of about 200 times that of sucrose, like APM, but has such further poorer sweetness profile that it is strong in late taste, bitter taste, astringent taste, peculiar taste, and stimulation when compared with APM. Therefore, it has been subjected to various approaches for the improvement, including the use in combination with APM for improving the sweetness profile (USP No. 4,158,068, and corresponding Japanese Patent Application Publication (Kokoku) No. 51262/'84). For example, the Japanese Patent Application Publication discloses the concurrent use of ACE-K and APM in a (weight) ratio of about 1:10 to 10:1, especially about 2:5 to 5:2, which, in turn, provides a sweetness profile closer to that of sucrose than that of either of the two.

Thus, various proposes have been made for improving the sweetness profile of APM, and each has been successful to some extent. Nevertheless, APM involves still such other problem concerning its solubility characteristics that an industrially produced APM powder (crystals) is difficult to dissolve in water

(because it has a tendency to form agglomerates (in Japanese, dama) and therefore, is not smooth to dissolve, and even without that, it has a lower rate of dissolution, and the like). The poorer solubility (i.e., poorer dissolution speed) due to such agglomeration and the like leads to the reduction in the production efficiency of food products or beverages to be supplemented with APM for imparting sweetness thereto, including soft drinks, which is, in turn, greatly disadvantageous to the commercial production thereof.

Some approaches for improving the solubility of APM have been proposed, including a method of graining (granulation). However, these approaches are still not satisfactory, e.g., because the solubility needs further improving (Japanese Patent Application Laid-open (Kokai) No. 346769/'92, and the like) and because a relatively larger amount of an excipient should be used concomitantly (Japanese Patent Application Laid-open (<u>Kokai</u>) Nos. 126855/'74, 19965/'75, 150361/'82, and the like). Incidentally, the concurrent use of ACE-K with APM disclosed in the above-mentioned Japanese Patent Application Publication (Kokoku) No. 51262/'84 is a concurrent use by merely mixing aqueous solutions of the two components (i.e., an aqueous ACE-K solution and an aqueous APM solution), and there is not made in the patent document any suggestion of the concurrent use of the two components, both in the form of granules, nor any mention of the solubility of either of the two in the granular form.

In view of the prior art discussed above, it is an object of the present invention to provide an excellent method for improving the solubility of APM.

(Disclosure of the Invention)

The present inventors have made an effort to achieve the object described above and found unexpectedly that when APM is prepared in an admixture with ACE-K into granules, the resultant granules undergo no agglomeration and exhibit a higher dissolution rate as compared with granules consisting of APM alone, i.e., that the overall solubility is improved, thus establishing the present invention.

Accordingly, the present invention relates to a granulated sweetener comprising Aspartame and Acesulfame-K as active ingredients, wherein the amount of the Acesulfame-K is 5 to 90 % by weight based on the total amount of both the components and wherein the maximum particle size of the granules is about 1,400 μ m or less.

The present invention will now be further described in greater detail below.

(a) Solubility of original powders and single-component granules:

An APM original powder, an ACE-K original powder and

granules produced by the method of Example 1 described below were respectively put in a dissolution tester to determine the respective time periods required for dissolution.

In the case of APM, those granules having a maximum particle size of about 1,400 µm or less required shorter time period for dissolution, as compared with the original powder, i.e., a solubility-improving effect by such granulation was observed, whereas no solubility-improving effect by such granulation was obtained concerning the APM granules having a particle size exceeding about 1,400 µm. On the contrary, the original powder of ACE-K exhibited an extremely high solubility as it was, and such granulation provided no particular improvement in solubility to the ACE-K (See Experiment 1).

Incidentally, a granulated sweetner comprising APM and ACE-K as active ingredients and having an ACE-K content of 90 % by weight or higher is not desirable because the bitter taste characteristic of ACE-K gets evident.

(b) Solubility of granules of a mixture (i.e., granulated mixture) and a mixture of granules:

Granules of a mixture of APM and ACE-K produced by the method of Example 1 (granules of mixture), and mixture of APM granules and ACE-K granules (mixture of granules) produced by the same method were respectively put in a dissolution tester to determine the time periods required for dissolution.

The results revealed that, insofar as the maximum

particle size of the granules is 1,400 µm or less, the dissolution rate of the granules of a mixture is always larger than that of the mixture of granules, with the ACE-K content (% by weight of the ACE-K present in the granules of a mixture, and, % by weight of the ACE-K granules present in the mixture of granules) being the same and the particle size being the same, and that the diference in dissolution rate between the two becomes more remarkable as the ACE-K content is increased and as the granule particle size is decreased, i.e., the dissolution-promoting effect of ACE-K on APM becomes more evident (See Experiment 2). The improvement in solubility observed with the granule of a mixture was considered to be due to the granule dissolution/disintegration-promoting effect by ACE-K, in addition to the prevention thereby of agglomeration and the prevention thereby of the floating on the surface of water.

Incidentally, an ACE-K content of 5 % by weight or less provides almost no dissolution-promoting effect by ACE-K, while that of 90 % by weight or higher causes the bitter taste of the ACE-K to get evident, as has been discussed above.

Therefore, the solubility-improving effect by ACE-K according to the present invention can be achieved using granules of a mixture of APM and ACE-K in which the ACE-K content is 5 to 90 % by weight and at the same time, the maximum particle size is about 1,400 μ m or less. Granules having a maximum

particle size of about 500 μm or less provides a further improvement in dissolution rate if the ACE-K content is 20 to 90 % by weight. Also, dissolution rate can be markedly improved, using granules having a maximum particle size of about 1,400 μm or less and at the same time, having an ACE-K content of 50 to 90 % by weight.

APM granules having an improved solubility as a result of admixture of ACE-K, i.e., the inventive granulated sweetener, can be produced by a known method. For example, a dry granulating process and also a wet granulating process can be employed. Specifically, granulation can be carried out by various methods such as mixing granulation, compacting granulation, extrusion granulation, fluidization granulation, rotation granulation, pulverization granulation, spray coating, tabletting or the like. However, for the purpose of less heat load and less complicated manufacturing process, it is commercially advantageous to employ a dry granulation process such as compacting granulation.

The inventive granulated sweetener can, depending on its use, contain a diluent or an excipient such as a sugar alcohol, an oligosaccharide and a dietary fiber as well as other high intense synthetic sweetener(s) such as Alitame, Saccharin, 3,3-dimethylbutylaspartylphenylalanine methylester and the like, like in the case of conventional intense synthetic

sweetener compositions, for the purpose of obtaining a better handling or improving the sweetness profile, as long as the improved solubility of APM according to the present invention is not affected adversely. A diluent or an excipient referred to herein includes a low intense sweetener such as sucrose, glucose and the like.

It is known that APM can be improved in solubility by means of granulation (Japanese Patent Application Laid-open (Kokai) No. 346769/'92, referred to above). On the other hand, ACE-K exhibits an extremely high solubility even in the form of an original powder, and exhibits no improvement in solubility even if granulated (as found by the present inventors). Therefore, if APM and ACE-K are to be used concurrently for some purpose, it would usually occur to those skilled in the art to place APM granules and an ACE-K original powder separately but concurrently in water, and it is difficult for those skilled in the art to expect that granules of a mixture of APM and ACE-K are dissolved more rapidly than when APM granules and an ACE-K original powder are placed separately but concurrently in water, and it is even more difficult to expect that APM can be improved in solubility by preparing it into granules of a mixture with ACE-K.

From the fact that an APM original powder, if granulated, can be improved in solubility, by agglomeration in a liquid being avoided, it could only occur to those skilled in the art

that an APM original powder, if mixed with ACE-K and granulated, does not agglomerate and has the same solubility as granules consisting of APM alone. Increased solubility of AMP when granulated in admixture with ACE-K as compared with granules composed only of APM is considered to be due to the simultaneous exertion of the disintegrating effect by ACE-K on granules having a larger particle size and the aggregation-preventing effect by ACE-K on granules having a smaller particle size, both of which are attributable to the addition of ACE-K.

The solubility of APM granules (i.e., granules consisting of APM alone) is just less unsatisfactory than that of an AMP original powder, and further improvement of the solubility is demanded by users. In accordance with the present invention, such further improvement of the solubility of APM has been realized, and also an excellent sweetener can be produced in which the sweetness profiles of both of APM and ACE-K are improved. While it would seem to those skilled in the art that a binder is considered to be essential for mixing and granulating APM together with ACE-K which is difficult to be integrated alone, APM serves as a binder unexpectedly in accordance with the present invention, whereby granulation of pure two components has been realized. A pure two-component sweetener composed only of ACE-K and APM, and containing no binder, diluent or excipient, can be extremely useful especially for beverage use.

(Best Mode for Carrying Out the Invention)

The present invention will be further described with reference to the following Experiments and Example.

Experiment 1 (Solubility of original powders and single-component granules):

A 1L dissolution tester (the Japanese Pharmacopoeia, Paddle method (container of 100 mm in inner size, 160 mm in height, having a hemispheric bottom of 50 mm in radius, and a net volume of 1,000 ml; paddle formed by sectioning a disc of 83 mm in size, and 3 mm in thickness, with parallel strings of 42 mm and 75 mm in length; 25 mm in distance between the lower end thereof and the container bottom), 100 rpm) was used together with 900 ml of water (20°C), in which 1 g of a sample was placed and examined for the time period required for dissolution (the endpoint being judged visually).

An APM original powder (average particle size being about 15 μ m, and maximum particle size being about 100 μ m; IB-type bundle-like crystals) and an ACE-K original powder (average particle size being about 250 μ m, and maximum particle size being about 500 μ m) were used as samples directly as they were and after granulated according to the method of Example 1, followed by sieving into various mesh size fractions.

The samples exhibited respectively time periods (min)

required for dissolution indicated in Table 1 shown below.

Table 1: Time period for dissolution (min)

Sample pa	rticle size	APM	ACE-K
Original p	owder	30	3
Granule	500 to 1,400 μm	32	3
	300 to 500 μm	18	2
	100 to 300 μm	18	2
	to 100 μm	29	3

Experiment 2 (Solubility of granules of a mixture and a mixture of granules):

Like in Experiment 1, the time periods required for dissolution of the granules were determined. The sample granules of mixtures were prepared by the method of Example 1 described below, using the same original powders as employed in Experiment 1. The sample mixtures of the granules were prepared by mixing APM granules of a certain particle size and ACE-K granules of a certain particle size as referred to in Experiment 1 at a certain ratio. 1 g of each sample was used in each trial.

In greater detail, as shown typically in the following Table 2, granules of mixtures of APM and ACE-K (granules of mixture) and mixtures of APM granules and ACE-K granules (mixture of granules) were subjected to the determination of the time period required for dissolution, with the mixing ratio

(ACE-K content) and the particle size being varied. Incidentally, a mixture of granules was obtained by mixing APM granules and ACE-K granules gently with a spatula. The results will be shown in the same table.

Table 2: Time periods for dissolution (min)

Ratio of ACE-K present (% by weight)		5 1)	2	0				90 (*3)	
Particle size	Granules	Mixture	Granules	Mixture	Granules	Mixture	Granules	Mixture	
(um)	of								
(μ m)	mixture	granules	mixture	granules	mixture	granules	mixture	granules	
500 to 1,400			24	31					
300 to 500	26	32	11	17	14	27	4	24	
100 to 300			4	18					
to 100			5	27					

^{*1,2,3 =} Values in these columns were of a non-sieved granules of a mixture or a mixture of granules.

Example 1 (Preparation of granules of a mixture of APM and ACE-K):

The same ACE-K as employed in Experiment 1 (average particle size being about 250 μm , and maximum particle size being about 500 μm) was pulverized by a compact laboratory centrifugal pulverizer (250 μm ϕ screen, 20,000 rpm) to obtain a pulverized ACE-K product whose average particle size was about 20 μm and whose maximum particle size was about 250 μm .

This pulverized ACE-K product was mixed with the same APM

as employed in Experiment 1 (average particle size being about 15 μ m, and maximum particle size being about 100 μ m) at various ratios and each resultant mixture was granulated using a dry roll mill (dry compaction and disintegration) and sieved to obtain fractions of granules of the mixture of APM and ACE-K having a varying particle size. Specifically, the dry compaction and the dry disintegration were performed using a compacting machine "ROLLER COMPACTER Model WP90 \times 30" (ex TURBO KOGYO), and the mixture was, upon compaction, fed to the compacting machine via a screw feeder (88 rpm) under a roll pressure of 4.9 Mpa at a roll speed of 12 rpm, and then disintegrated using a fine granulator screen of 12 mesh size (pore size being 1,400 μ m). The granules were sieved using a JIS (Japanese Industrial Standard) standard sieve.

The granules of the mixtures of APM and ACE-K having various mixing ratios and various particle sizes thus obtained were used for the test in Experiment 2 described above.

(Industrial Applicability)

By mixing and granulating Aspartame (APM) and Acesulfame-K (ACE-K) according to the invention, the poor solubility (i.e., poor dissolution speed) of APM can be improved markedly, and a sweetener having an excellent sweetness profile can readily be prepared.

CLAIMS

- 1. A granulated sweetener comprising Aspartame and Acesulfame-K as active ingredients, wherein the amount of the Acesulfame-K is 5 to 90 % by weight based on the total amount of both the components and wherein the maximum particle size of the granules is about 1,400 μ m or less.
- 2. The granulated sweetener according to Claim 1, wherein said amount of the Acesulfame-K is 50 to 90 % by weight.
- 3. The granulated sweetener according to Claim 1, wherein said amount of the Acesulfame-K is 20 to 90 % by weight and wherein said maximum particle size of the granules is about 500 μm or less.

ABSTRACT

Herein is disclosed a granulated sweetener comprising Aspartame and Acesulfame-K as active ingredients, wherein the amount of the Acesulfame-K is 5 to 90 % by weight based on the total amount of both the components and wherein the maximum particle size of the granules is about 1,400 µm or less, in which granulated sweetener the poorly dissoluble, high intense synthetic sweetener Aspartame (APM) is improved in solubility.

Declaration and Power of Attorney For Patent Application

特許出願宣言書及び委任状

Japanese Language Declaration

日本語宣言書



As a below named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled. GRANULAR SWEETENER
the specification of which is attached hereto. was filed on as United States Application Number or PCT International Application Number and was amended on (if applicable).
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.
I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

Japanese Language Declaration



私は、米国法典第35編119条 (a) - (d) 項又は365条 (b) 項に基づき下記の、米国以外の国の少なくとも一ヵ国を指定している特許協力条約365 (a) 項に基づく国際出願、又は外国での特許出願もしくは発明者証の出願についての外国優先権をここに主張するとともに、優先権を主張している、本出願の前に出願された特許または発明者証の外国出願を以下に、枠内をマークすることで、示しています。

Prior Foreign Application(s)

外国での先行出願

L

9/352728	JAPAN
(Number)	(Country)
(番号)	(国名)
(Number)	(Country)
(番号)	(国名)

私は、第35編米国法典119条(e)項に基づいて下記の米国特許 出願規定に記載された権利をここに主張いたします。

(Application No.) (出願番号)

(Filing Date) (出願日)

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PCT/JP98/05236	20 November 1998
(Application No.)	(Filing Date)
(出願番号)	(出願日)
(Application No.)	(Filing Date)
(出願番号)	(出顧日)

私は、私自信の知識に基づいて本宣言書中で私が行なう表明が 真実であり、かつ私の入手した情報と私の信じるところに基づ く表明が全て真実であると信じていること、さらに故意になさ れた虚偽の表明及びそれと同等の行為は米国法典第18編第1001 条に基づき、罰金または拘禁、もしくはその両方により処罰され ること、そしてそのような故意による虚偽の声明を行なえば、 出願した、又は既に許可された特許の有効性が失われることを 認識し、よつてここに上記のごとく宣誓を致します。 I hereby claim foreign priority under Title 35, United States Code, Section 119 (a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

	•	Claimed 権主張
22 December 1997	Q	
(Day/Month/Year Filed) (出願年月日)	Yes はい	No いいえ
(Day/Month/Year Filed) (出願年月日)	ソes はい	し No いいえ

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States previsional application(s) listed below.

(Application No.) (Filing Date) (出願番号) (出願日)

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of application.

(Status: Patented, Pending, Abandoned) (現況:特許許可済、係属中、放棄済)

(Status: Patented, Pending, Abandoned) (現況:特許許可済、係屬中、放棄済)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Page 2 of _4

Japanese Language Declaration (日本語宣言書)

委任状:私は下記の発明者として、本出願に関する一切の手続きを米特許商標局に対して遂行する弁理士または代理人として、 下記の者を指名いたします。

(弁護士、または代理人の指名及び登録番号を明記のこと)

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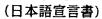
	·		
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(第三以降の共同発明者についても同様に記載し、署名すること)

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Japanese Language Declaration



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第五の共同発明者の氏名		Full name of fifth joint inventor, if any		
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第六の共同発明者の氏名		Full name of sixth joint inventor, if any	
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(第六またはそれ以降の共同発明者に対しても同様な情報および署名を提供すること。)

(Supply similar information and signature for third and subsequent joint inventors.)

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